DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 13, 2015

Cutting Edge Spine, LLC
Mr. John Souza, Sr.
Director of Engineering
101 Waxhaw Professional Park Drive, Suite A
Waxhaw, North Carolina 28173

Re: K150321
Trade/Device Name: EVOS Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 2, 2015
Received: July 7, 2015

Dear Mr. Souza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150321

Device Name
EVOS Lumbar Interbody System

Indications for Use *(Describe)*
The EVOS Lumbar Interbody System (EVOS device) is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

The EVOS Lumbar Interbody System is intended to be used with autologous bone graft to facilitate fusion. It is to be used in patients who have had six months of non-operative treatment and is to be implanted via a direct posterior or transforaminal approach. The EVOS CURVED devices are implanted singly, while the EVOS ROTATE and EVOS STRAIGHT devices may be implanted singly or in pairs in the lumbosacral spine. The EVOS Lumbar Interbody System is intended to be used with supplemental fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. SUBMITTER

Cutting Edge Spine, LLC
101 Waxhaw Professional Park Dr., Suite A
Waxhaw, NC 28173

Tel: (704) 243-0892 ext 12
Fax: (704) 731-2559

Contact Person: John Souza Sr., Director of Engineering
Date Prepared: February 06, 2015

II. DEVICE

Name of Device: EVOS Lumbar Interbody System
Common or Usual Name: Intervertebral fusion device with bone graft, lumbar
Classification Name: Intervertebral body fusion device (21 CFR 888.3080)
Regulatory Class: II
Product Code: MAX

III. PREDICATE DEVICE

	510(k) Number	Device	Manufacturer
Primary Predicate	K102957	EVOL Intervertebral Body Fusion Device	Cutting Edge Spine, LLC
Additional Predicate	K071724	Lucent Intervertebral Body Fusion Device	Spinal Elements
Additional Predicate	K073291	Capstone Spinal System	Medtronic
Additional Predicate	K120368	Capstone Control Spinal System	Medtronic

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The EVOS Lumbar Interbody System is an Intervertebral Body Fusion System for the lumbar spine. The EVOS Lumbar Interbody System includes surgical instruments to deliver the EVOS devices via a Posterior or Transforaminal approach. The generally rectangular design of the EVOS device

incorporates an internal cavity for insertion of biological bone growth material through the top and bottom openings, as well as four small transverse holes (two on each side) that are designed to enhance bony ingrowth. Each device has a series of ridges or "teeth" on the top and bottom surfaces that are designed to ensure strong anchoring on the vertebral body endplates and resist backing out of the implant. The EVOS devices are provided sterile (gamma irradiated) for single use.

The EVOS device is made of radiolucent PEEK-OPTIMA® LT1 or PEEK-OPTIMA® HA Enhanced material. In addition, tantalum beads are embedded in the spacers to allow for radiographic visualization. The geometric shape of the EVOS devices are categorized as either STRAIGHT, CURVED, or ROTATE. All are available in a range of sizes, as well as flat and biconvex endplates, and with various degrees of lordosis to accommodate variations in patients' anatomy. Most of the EVOS STRAIGHT devices are offered with an option of a Standard nose, Wide nose, or Narrow nose. The devices are available in various heights, widths, and lengths to accommodate various surgical technique options.

V. INDICATIONS FOR USE

The EVOS Lumbar Interbody System (EVOS device) is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

The EVOS Lumbar Interbody System is intended to be used with autologous bone graft to facilitate fusion. It is to be used in patients who have had six months of non-operative treatment and is to be implanted via a direct posterior or transforaminal approach. The EVOS CURVED devices are implanted singly, while the EVOS ROTATE and EVOS STRAIGHT devices may be implanted singly or in pairs in the lumbosacral spine. The EVOS Lumbar Interbody System is intended to be used with supplemental fixation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Intervertebral Body Fusion through a Posterior or Transformanial approach is the technological principle for both the subject and predicate devices. It is based on the use of surgical instrumentation to insert PEEK implants into the intervertebral space in order to assist in fusion. At a high level, the subject and predicate devices are based on the following same technological elements:

- Indications for Use
- Structural support mechanism

VII. PERFORMANCE DATA

The EVOS device was tested in compliance with FDA's guidance document titled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" and demonstrated substantially equivalent performance characteristics to the identified predicate devices.

The EVOS device has been tested in the following test modes:

- Mechanical Testing on the final device that has been gamma irradiated and aged.
  - Expulsion Testing
  - Static Axial Compression per ASTM F2077
  - Static Compressive Shear per ASTM F2077
  - Static Testing in Subsidence per ASTM F2267
  - Dynamic Axial Compression per ASTM F2077

VIII. CONCLUSIONS

The overall technology characteristics and mechanical performance data lead to the conclusion that the EVOS Lumbar Interbody System is substantially equivalent to the EVOL Intervertebral Body Fusion Device from Cutting Edge Spine (K102957), the Lucent Intervertebral Body Fusion Device from Spinal Elements (K071724), the Medtronic Capstone Spinal System (K073291), and the Medtronic Capstone Control Spinal System (K120368).